

Lab Working Group Call 5/26/04

Participants: Harvey Kaufman, John Eckfeldt, Michael Welch, Gary Myers, Mauro Panteghini, Neil Greenberg, Greg Miller, Ethan Hausman, Jim Fleming, Andy Levey, Tom Hostetter, and Elisa Gladstone

Next Steps:

- ➤ Harvey will send Gary his revised section for the manuscript by June 4.
- ➤ Gary will put together the list of what he has for the manuscript and what he needs by June 4.
- ➤ Gary will put the manuscript together and send out by June 11.
- > John and Michael will talk off-line about the status of the NIST frozen serum reference materials for creatinine.
- ➤ NIST is still working on the secondary reference method and testing it in the next few days.
- ➤ Before collecting samples for the commutability testing, it would be best to figure out the reference method that will be used, which preferably will be the NIST's new HPLC-MS method.
- ➤ Michael will keep John posted on how the HPLC method works. John would like to know if any problems arise.
- ➤ John is going to push CAP to introduce their new creatinine Linearity Survey this fall rather than next spring. If they agree, we could let the manufacturer's know of it's availability at the July Manufacturers' Forum.

Manufacturers' Forum:

The near final version of the "state of the art paper" should be available by July 1 to prepare for comments from the working group.

The agenda for the forum will be as follows:

- 1. Overview of NKDEP (Hostetter)
- 2. MDRD Equation for Adults (Hostetter) mention pediatric equation; incorporate "Impact of Standardizing Creatinine"
- 3. Current Status of Creatinine Measurement (Miller)
- 4. Approaches to Standardization of Creatinine (Myers/Welch)
- 5. European EC 4 and any other international creatinine standardization projects (Welch)

- ➤ The presentations and discussion will each take about an hour. Each of the five presentations should be roughly 10 minutes each.
- ➤ Andy can provide slides to Tom on the MDRD equation for the Manufacturer's Forum meeting.
- Andy will send graph relating estimated GFR with and without calibration using data on calibration differences reported in the Ross paper describing the 1994 CAP fresh frozen serum project's results.
- ➤ Mauro will draft his thoughts in a paragraph on the clinical requirements section and submit to Gary.
- ➤ The originally proposed topic of "Impact of Standardization" will be combined with the first two agenda items Overview of NKDEP and MDRD Equation.
- ➤ Need to get list/names from Neil and invite LIS vendors to the manufacturer's forum.
- ➤ The slides for the forum will be due two weeks prior to the meeting July 12. The presentations will be circulated to the group for comments on a conference call that will be held on July 19 at 10:00 am EDT. Speakers and any other interested WG members should participate.
- NKDEP will put downloadable versions of the PowerPoint slides of the Manufacturer Forum presentations and the draft version of the state of the art manuscript on NKDEP's website on the Lab WG's page. The manuscript will clearly indicate "draft not for citation" on the website and on each page of any downloaded manuscript.
- A dozen copies of the manuscript will be available at the forum.

Lab WG 7/29/04 meeting (July 29 from 10:30-12:30 pm)

> Draft agenda:

- 1. CAP linearity study
- 2. NIST ref. materials
- 3. Update on NIST secondary reference method (HPLC-MS) method (Welch)
- 4. Update on NIST reference material commutability testing (Eckfeldt)
- 5. Update on new CAP Linearity Survey Pilot (Eckfeldt)
- 6. Review comments from the manufacturer's meeting
- ➤ If anyone has items to add to the Lab WG meeting at the AACC, please send them to Elisa, Tom, John, and Laura by email.
- > John will follow up with IFCC members to see if they would like to attend the working group meeting.

Important Dates:

July 1 – Finalize manuscript to send around for comments

July 12 – Presentations due to Elisa to circulate for comments

July 19 at 10:00 am EDT – Conference call with speakers and rest of working group

July 26, 10-12:00 pm – Manufacturer's forum (Westin Bonaventure Hotel, Beaudry B)

July 29, 10:30-12:30 pm – Lab Working group meeting (Westin Bonaventure Hotel, Los Feliz room)